

VIII. 510(k) Summary

K023835
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SUBMITTER: DePuy AcroMed™, Inc.
325 Paramount Drive
Raynham, MA 02767-0350 USA

JAN 29 2003

CONTACT PERSON: Karen F. Jurczak

DATE PREPARED: November 15, 2002

PROPRIETARY NAME: Devex Mesh™ System

CLASSIFICATION NAME: Implant, fixation device
Spinal intervertebral body fixation orthosis device

PREDICATE DEVICE: Surgical Titanium Mesh System (K003043, K020522)
Stackable Cage System (K990148, K001340)

INTENDED USE: The Devex Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The Devex Mesh System is also indicated for treating fractures of the thoracic and lumbar spine.

The Devex Mesh System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The Devex Mesh System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the Surgical Titanium Mesh System include DePuy AcroMed titanium plate or rod systems (e.g. Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, Monarch and Profile).

MATERIALS: Titanium alloy (Ti-6Al-4V)

PERFORMANCE DATA: Biomechanical testing, including static axial compression and dynamic axial compression, were conducted.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 2003

Mr. Frank Maas
Director, Regulatory Affairs
DePuy AcroMed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K023835

Trade/Device Name: Devex Mesh™ System
Regulation Number: 21 CFR 888.3060
Regulation Name: Vertebral Body Replacement Device
Regulatory Class: Class II
Product Code: MQP
Dated: January 8, 2003
Received: January 9, 2003

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

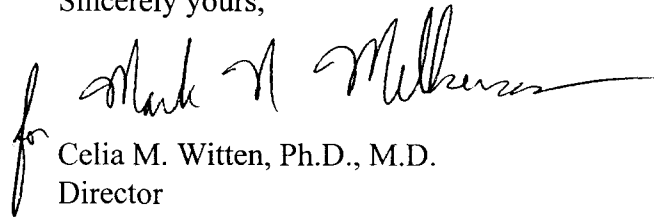
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Frank Maas

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use

510(k) Number (if known): K023835

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Device Name: Devex Mesh™ System

Indications For Use:

The Devex Mesh System is indicated for use in the thoracolumbar spine (T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)

OR Over-The-Counter Use: _____

for Mark A. Miller
(Division Signatory)
Director, Division of Regulatory and Biotechnology

510(k) Number: K023835